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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,042	09/29/2000	Yasuyuki Nozaki	07898-059001	1694

38327 7590 10/20/2004
REED SMITH LLP
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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,042

Applicant(s)

NOZAKI ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 11, 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/04 has been entered.

Information Disclosure Statement

The IDS filed 7/26/04 has been considered.

Election/Restrictions

Claims 1-4, 11 and 16-17 are generic and allowable. Claim 5, directed to an elected species, is also allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 6-10, directed to the species of states of an individual's tissue, species of individual, individual's sites, presence or absence of an artificial condition, and combinations of experiment cases, are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

However, claims 12-15, directed to a nonelected Invention, remain withdrawn from consideration since they are directed to a patentably distinct

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Invention and do NOT depend upon or otherwise include all the limitations of an allowed generic claim as required by 37 CFR 1.141.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 10 limit experiment cases to comprise "individual's sites". The specification does not define the phrase "individual's sites" and there is no commonly accepted meaning for the phrase in the art. The specification exemplifies some "individual's sites" as stomach, large intestine, and heart on page 22, but does not specifically define "sites" anywhere. The examples indicate that "individual's sites" may be tissues, organs, organ or tissue systems

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(e.g. cardiovascular system vs. digestive or gastric system?), etc. As it is unclear what limitation applicant intends for an "individual's sites", the claims are indefinite.

Claims 9 and 10 limit experiment cases to comprise "presence and absence of an artificial condition." The specification does not define an "artificial condition" and there is not commonly accepted meaning for the phrase in the art. The specification exemplifies "presence and absence of an artificial condition" on page 22 as "before and after drug administration, but fails to state whether the "artificial condition" is administration of a drug, the condition of a patient before drug administration, or the condition of a patient after drug administration. For example, a diabetic may be considered to be in an "artificial condition" (i.e. unhealthy) before administration of insulin, but in a "normal" or healthy condition after insulin administration. The specification does not specifically define either an "artificial condition" or the "presence and absence of an artificial condition" anywhere. As it is unclear what limitation applicant intends for an "presence and absence of an artificial condition", the claims are indefinite.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the amendment filed 7/26/04 is supported by the original specification on pages 13 and 22. Applicant's arguments filed 7/26/04 with regard to the prior art are persuasive.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-7, 11, and 16-17 are allowed. Claims 8-10 are rejected and claims 12-15 remain withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
10/18/04